antigen, is allowable as amended but has maintained rejections of Claims 3-10, directed to an antibody against the 40 kDal antigen as well as methods of using these antibodies and kits containing these antibodies, stating in support of this rejection "[m]oreover, no demonstration of a lack of cross-reactivity or specificity between the Applicant's antigen and the Bast et al. antibody is of record."

In further response to the rejections, Applicant submits a Declaration in accordance with the provisions of 37 C.F.R §1.132 which provides additional data relative to establishing that the Bast et al. antibody does not cross react with the Applicant's 40 kDal antigen and hence establishes that Applicant's antibody against the 40 kDal antigen is patentably distinct from the Bast et al. antibody. This data was generated, in part, to respond to the Examiner's comments in the Advisory Action. Since this data was heretofore unavailable, it could not have been included with the previously filed response to the final rejection. Accordingly, Applicant has diligently prepared and submitted the accompanying declaration which incorporates the recent data supporting the patentability of Claims 3-10. Applicant respectfully requests reconsideration of the subject application in light of direct experimental evidence showing that the Bast et al. antibody does not cross react with Applicant's 40 kDal antigen.

Before further discussion of the data and to insure consistency in nomenclature, Applicant notes that the Bast et al. antibody, as denoted by the Examiner, is generally referred to as the OC125 antibody in the scientific literature. In addition, Applicant uses "subunit" interchangeably with "subspecies" in accordance with Applicant's response dated April 20, 1989.

Specifically, the Examiner has alleged that the antibodies to the 40 kDal subunit of the CA125 antigen (Claims 3 and 4) are not patentably distinct from the monoclonal antibody described by Masuno et al. and Bast et al. (the OC125 antibody), the references which form the basis of the rejection of Claims 3 and 4 under 35 U.S.C. §102(b). The Examiner's rejection having been made because the specificity of the OC125 antibody with respect to the 40 kDal subunit has not been determined, i.e., allegedly, it has not been shown that the epitope(s) to which the OC125 antibody binds does not reside in the 40 kDal subunit. Hence, to show that the OC125 antibody is distinct from the subject antibodies, one must demonstrate that the OC125 antibody does not bind to the 40 kDal subunit of the CA125 antigen. This can be accomplished by performing a Western blot (immunoblot) of the multisubunit CA125 antigen prepared from a source known to have the 40 kDal subunit. Such an experiment thus establishes to which subunit of the CA125 antigen that the OC125 antibody binds. An experiment demonstrating that the OC125 antibody does not cross react with the 40 kDal subunit is described in the accompanying Declaration.

Briefly, the CA125 antigen was purified from ascites fluid obtained from a patient with ovarian cancer. The purification of the CA125 antigen was carried out as described in the Specification at Page 17, line 1 to Page 18, line 3. Electrophoresis of the purified CA125 antigen under denaturing conditions (i.e., standard SDS-PAGE) indicates that the CA125 antigen from this source is composed of several subunits including the 40 kDal subunit (see Fig. 1 of the Declaration). This is the result taught in accordance with the present invention. Further analysis was then conducted to establish which component(s) of the CA125 antigen the OC125 antibody

reacts with, under conditions which assure that the 40 kDal subunit is present. A Western blot of this CA125 antigen preparation using the OC125 antibody is shown in Fig. 2 of the Declaration. The results indicate that the OC125 antibody binds to the 200 kDal subunit of the CA125 antigen and not to the 40 kDal subunit.

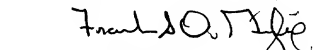
Moreover, this result is in agreement with the results of Davis et al. which were described at Page 5, Lines 17-24 in Applicant's response dated April 20, 1989.

Applicant has clearly demonstrated that the OC125 antibody does not bind to the 40 kDal subunit of the CA125 antigen. Accordingly, the subject antibodies against the 40 kDal subunit (Claims 3 and 4) are patentably distinct from the OC125 antibody. The new evidence provided by the Declaration is thus deemed to overcome the Examiner's rejection of Claims 3 and 4 under 35 U.S.C §102(b) and withdrawal thereof is respectfully requested.

The Examiner further rejected Claims 5-10 under 35 U.S.C. §103 as allegedly rendered obvious by Masuno et al. and Bast et al. in view of Petska or the WO patent 85/00663. Applicant submits that the Declaration submitted herewith and the foregoing remarks with respect to establishing that the subject antibodies are patentably distinct with respect to the OC125 antibody are sufficient to overcome the rejection of Claims 5-10 under 35 U.S.C. §103 in that the secondary references, directed to methods of immunological assays using distinctly different antibodies than the subject antibodies, fail to ameliorate the deficiencies of the primary references in any regard; therefore, withdrawal of this rejection is also respectfully requested.

Thus in view of the accompanying Declaration and foregoing Remarks, the present case is deemed to be in condition for allowance which action is earnestly solicited.

Respectfully submitted,



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